

Remarks

Claims 1-18 were pending in the subject application. By this Amendment, the applicants have amended claim 1 and have cancelled claims 2-4. Support for the amendments to the claims can be found throughout the specification and the claims as originally filed. No new matter has been added by these amendments. Accordingly, claims 1 and 5-18 are before the Examiner for consideration.

The amendments to the claims have been made in an effort to lend greater clarity to the claimed subject matter and to expedite prosecution. The amendments should not be taken to indicate the applicants' agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

Claims 1-18 have been rejected under 35 U.S.C. 112, first paragraph. The applicants respectfully traverse this ground for rejection to the extent that it might be applied to the claims now presented for examination.

The Office Action indicates that the specification does not enable the skilled artisan to make and use the invention commensurate in scope with the claims. Please note that the applicants have amended the claims herein to eliminate reference to skin cancer. Claim 1 now recites only sunburn, inflammation, and skin aging.

It is important to bear in mind that for an invention to be enabled under the first paragraph of §112, the specification need only teach a person of ordinary skill in the art "how to make" and "how to use" the invention. See, e.g., *In re Angstadt*, 537 F.2d 498, 190 USPQ 214 (CCPA 1976).

It should be noted that the requirement for some experimentation and/or screening does not necessarily make a claim non-enabled. "Enablement is not precluded by the necessity for some experimentation such as routine screening. . . . A considerable amount of experimentation is permissible, if it is merely routine . . ." (emphasis added). *In re Wands*, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988).

The specification provides guidance to one skilled in the art to practice the invention without undue experimentation. Also, the applicants have disclosed multiple examples of cellular and mice experiments demonstrating the effectiveness of the claimed invention.

The examples provided by applicants in the specification provide sufficient guidance to the skilled artisan to practice the amended claims without undue experimentation. For the reasons set forth above, the applicants believe that they have fulfilled the requirements of 35 USC §112. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

Claims 1-11, 13, and 15-16 have been rejected under 35 U.S.C. 102(b) as being anticipated by Osaki *et al.* (J. Immunol., Vol. 160, p. 1742-1749). The applicants respectfully traverse this ground for rejection to the extent that it might be applied to the claims now presented for examination.

The applicants have amended the claims herein in order to clarify the subject matter of the instant invention. In particular, claim 1 has been amended to recite a method of treating sunburn, inflammation, or skin aging. Of note, the claims of the subject invention now do not recite skin cancer.

It is a basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra*; *Kalman [v. Kimberly-Clarke]*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

The Osaki *et al.* reference focuses on treatment of a particular melanoma, including the observation of changes in tumor area in various experimental environments. In contrast, the subject invention is a method for treating the specific skin disorders of sunburn, inflammation,

and skin aging. The Osaki *et al.* reference does not disclose or suggest treating the conditions as now claimed by the current applicants.

Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. 102(b) based on the Osaki *et al.* reference.

Claims 1-13 and 15-18 have been rejected under 35 U.S.C. 102(e) as being anticipated by Gillespie *et al.* (US 6,896,880). The applicants respectfully traverse this ground for rejection to the extent that it might be applied to the claims now presented for examination. Specifically, the cited reference does not disclose or suggest treating the specific conditions now recited in the applicants' claims.

The claimed method is drawn to the treatment of sunburn, inflammation, and/or skin aging. This differs significantly from the disclosure of the Gillespie *et al.* reference, which focuses on excessive osteoclast formation. As noted above, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The Gillespie *et al.* reference does not teach the use of IL-18 to treat the specific conditions recited in the applicants' claims.

The Office Action acknowledges that the cited reference does not in fact teach the treatment of the disorders associated with the subject invention; however, the Office Action suggests that the cited reference inherently anticipates the claimed method.

The applicants respectfully point out that for a claim to be anticipated under the principles of inherency, the subject of a single prior art reference must necessarily function in accordance with the limitations of the process or method claimed. *In re King*, 801 F.2d 1324, 1326, 231 USPQ 136, 138 (Fed. Cir. 1986). Further,

the doctrine of inherency is available only when the prior inherent event can be established as a certainly. That an event may result from a given set of circumstances is not sufficient to establish anticipation. . . . A prior inherent event cannot be established based on speculation, or where a doubt exists (emphasis added). *Ethyl Molded Product Co. v. Betts Package Inc.*, 9 USPQ 2d 1001, 1032-33 (E.D. KY 1988).

The method of use in Gillespie *et al.* focuses on osteoclast formation; there is no teaching or even suggestion relating to sunburn, inflammation, or skin aging.

“In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

The method of use in the cited reference is based on osteoclastogenic inhibition, which is very different from the physiological bases for the claimed method of treating sunburn, inflammation, and skin aging. Therefore, it cannot be said that the characteristics of the claimed method would “necessarily flow” from Gillespie *et al.* Accordingly, the applicants respectfully request reconsideration of the claims in light of the amendments and request withdrawal of the rejection under 35 U.S.C. 102(e).

Claim 14 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Osaki *et al.* The applicants respectfully traverse this ground for rejection because the cited reference does not disclose or suggest the applicants’ advantageous method, as now claimed.

The shortcomings of the Osaki *et al.* reference with respect to the current invention have been discussed above. Given the important differences in the underlying teachings of the cited reference compared to the critical characteristics of the current invention, there would be no reason to modify the teachings of the Osaki *et al.* reference to arrive at the current invention.

It is well established in the patent law that the mere fact that the purported prior art could have been modified or applied in some manner to yield an applicant’s invention does not make the modification or application obvious unless “there was an apparent reason to combine the known elements in the fashion claimed” by the applicant. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ____ (2007). Furthermore, an applicant’s invention is not “proved obvious merely by demonstrating that each of its elements was, independently, known in the (purported) prior art.” *Id.*

The Court of Customs and Patent Appeals was faced with an analogous situation in *In re Hayashibara and Sugimoto*, 188 USPQ 4 (CCPA 1975). The PTO Board of Appeals had affirmed a §103 rejection, and the CCPA reversed, stating:

Turning to the . . . rejection . . . for obviousness under 103, we agree with appellants that there is nothing in the reference which would lead those of ordinary skill in the art to employ [the substance] as appellants do in the product of claim 11. The reference does not teach [the substance] as possessing any of the characteristics or functions upon which appellants' claimed invention depends (emphasis added).

The cited reference does not disclose or suggest the subject matter of the applicants' claim 14. Nor would there be any reason for the skilled artisan to modify the teachings of the cited reference to arrive at the current invention. Accordingly, the applicants respectfully request reconsideration and withdrawal of the obviousness rejection under 35 U.S.C. §103 based on the *Osaki et al.* reference.

Claim 14 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Gillespie *et al.* The applicants respectfully traverse this ground for rejection because the cited reference does not disclose or suggest the applicants' advantageous method, as now claimed.

The shortcomings of the Gillespie *et al.* reference with respect to the current invention have been discussed above. Given the important differences in the underlying teachings of the cited reference compared to the critical characteristics of the current invention, there would be no reason to modify the teachings of the Gillespie *et al.* reference to arrive at the current invention.

As expressed by the CAFC, to support a §103 rejection, “[b]oth the suggestion and the expectation of success must be founded in the prior art...” *In re Dow Chemical Co.* 5 USPQ 2d 1529, 1531 (Fed. Cir. 1988). In the current case, there is no reason to expect that optimizing dosages of IL-18 in the context of addressing excessive osteoclast formation would have any relevance for treating sunburn, inflammation, or skin aging.

An assertion of obviousness without the required suggestion or expectation of success in the prior art is tantamount to using applicant's disclosure to reconstruct the prior art to arrive at the subject invention. Hindsight reconstruction of the prior art cannot support a §103 rejection, as was specifically recognized by the CCPA in *In re Spinnoble*, 56CCPA 823, 160 USPQ 237, 243 (1969).

The cited reference does not disclose or suggest the subject matter of the applicants' claim 14. Nor would there be any reason for the skilled artisan to modify the teachings of the cited reference to arrive at the current invention. Accordingly, the applicants respectfully request reconsideration and withdrawal of the obviousness rejection under 35 U.S.C. §103 based on the Gillespie *et al.* reference.

In view of the foregoing remarks and the amendments above, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



David R. Saliwanchik
Patent Attorney
Registration No. 31,794
Phone: 352-375-8100
Fax No.: 352-372-5800
Address: P.O. Box 142950
Gainesville, FL 32614-2950

DRS/la